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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,766	02/08/2002	Marvin J. Slepian	MJS 104	2905

23579 7590 10/04/2004

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,766	SLEPIAN, MARVIN J.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *4,5,8-12,27,30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,13-26,28,29,31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/27/04, 8/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a response to an amendment filed 8/26/04. Claims 3-6, 8-15 and 23-33 have been amended. Claims 1-33 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 8/26/04 is acknowledged. The traversal is on the following grounds. 1) Applicants' state that the separate inventions of Groups I-V are encompassed by independent claims 1, 15 and 25 as amended and the relatedness of these inventions is allegedly verified by use of linking claim practice recited in the restriction requirement. Applicants reference MPEP 809, which teaches linking claim practice. 2) Examiner has focused on the "results to be achieved" which are not elements of the claimed invention, devices or kits. Therefore, it does not affect the determination of the patentability of claims 1-33. Rather, the different therapeutic agents do not require different steps but use the same step of locally penetrating the body of an organ, organ component or tissue structure and depositing the agent using the same device or kit.

This is not found persuasive because of the following reasons. 1) Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of administering drugs (group I) or polymers (group II) or cells (group III) or nucleic acids (group IV) or devices (group V) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs a function using a structurally and

functionally divergent material. Moreover, the methodology and materials necessary for each of the inventions is different. For example, the administration of the drugs requires distinct preparation of the drugs as well as actual administration means, given the physiological and biochemical effects mediated by the drugs, the means of assessing drug delivery and effect are different from that of any other method. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-V are patentably distinct.

While applicants have argued that the criteria for establishing the inventions are distinct has focused on "results to be achieved", the criteria for establishing distinctness has been based upon the actual recited elements and methods related to these elements as detailed above. Furthermore, the distinct steps and products require separate and distinct searches as a search for art for methods and compositions related to drugs would not overlap a search for art for methods related to deposition of cells or nucleic acids or devices or polymers. As such, it would be burdensome to search the inventions of Groups I-V together.

That claims 1-2, 14-28 and 31 link the inventions of Group I-V has been addressed in linking claim practice as set forth in the office action mailed 7/26/04. Briefly, upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

The requirement is still deemed proper and is therefore made FINAL. However, upon reconsideration, claims 26 and 27 have been withdrawn from examination as being drawn to non-elected subject matter. The claims are drawn to kits comprising devices for depositing polymers into a midzone and as such are part of Group II. Therefore, claims 1-3, 6-7, 13-25 and

28, 29, 31 and 33, drawn to a method and devices of treatment comprising locally penetrating and entering the body of an organ and depositing drugs such as peptides, proteins, steroids, vitamins and hormones in the midzone, are under examination in the instant application.

Oath/Declaration

In response to a notice to file missing parts mailed 3/12/02, applicants have indicated the filing of a signed copy of the oath in a letter filed 5/10/02. However, a copy of the signed oath cannot be found in the application and, therefore, a new copy of the signed Oath is required.

Information Disclosure Statement

Information Disclosure Statements filed 6/27/02 and 8/3/04 have been identified and the documents considered.

Specification

The brief description of drawings is objected to because Figure 2 is described in the Brief Description of Drawings as comprising Figure 2A -2E and 2G-2H. However, Figure 2 does not contain a 2H portion but does contain a 2F portion. Appropriate correction is required.

Claim Objections

Claims 2, 3, 7, 14-16 and 25 are objected to because of the following informalities: Claims 2, 3, 14, 15 and 25 are drawn to non-elected subject matter and the claims should be drafted without the nonelected subject matter. Claim 7 is objected to as PDGF, FGF, TGF,

EDGF, NGF, ILGF and SPARC are abbreviated. The first occurrence of an abbreviation should be spelled out for clarity. Claim 16 recites, "rigid made" and appears to be missing a punctuation or conjunction between the words "rigid" and "made". Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-3, 6-7, 13-25, 28, 29, 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of "a method of treatment" are unclear. The method as recited does not set forth any steps for treatment. The method simply claims that an organ, organ component or tissue structure is accessed.

Claim 1 is vague and indefinite in that the metes and bounds of "locally penetrating" are unclear. "Locally" is a relative term for which neither the specification nor the prior art prescribes a standard meaning. Therefore, it is unclear what criteria are used to determine that the structure has been "locally" penetrated.

Claim 1 is vague and indefinite in that the metes and bounds of entering the body of an "organ, organ component or tissue structure" are unclear. The only recited outcome of entering any of these structures is "access to endomural zones of an organ". If the structure entered is

actually a tissue structure or an organ component such as vessels this is not encompassed by accessing the endomural zones of an organ.

Claim 2 is vague and indefinite in that the metes and bounds of "midzone" are unclear. Neither the specification nor the prior art define the "midzone" such that a skilled artisan would know where the therapeutic agents would be deposited. The specification defines the endomural zone as the middle or middle zone of the organ. It is unclear if this is the same as the "midzone" or if the "midzone" is a separate location in the organs, organ components or tissue structures.

Claim 13 recites the limitation "the therapeutic factors" in claim 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 15 and 25 are vague and indefinite in that the metes and bounds of "endomural tissue" are unclear. Applicants have described the endomural zone of an organ or tissue structure or organ component but have not described an "endomural tissue".

Claims 15 and 25 are vague and indefinite in that the metes and bounds of "end penetrating" are unclear. It is unclear to what "end" refers. Furthermore, the specification discloses means of penetrating the endoluminal however there is no disclosure as to what means are required for "end penetration".

Claims 15 and 25 are vague and indefinite in that the metes and bounds of "causing minimal collateral damage" are unclear. It is unclear to what damage has been "caused" and furthermore to what "collateral" refers, as there is nothing collateral to the cutting means.

Claims 15 and 25 are vague and indefinite in that the metes and bounds of "cutting means" are unclear. Furthermore, the metes and bounds of "means for delivery of therapeutic agents into endomural tissue" are unknown. Means plus function language must be accompanied

by an adequate disclosure showing what that language means. In re Donaldson Co., 16 F.3d 1189,1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994). In the instant case, applicants have not disclosed what is meant by "cutting means". Furthermore, while means for delivery have been disclosed, those means, which are essential for delivery to endomural tissue, have not been disclosed.

Claim 17 is vague and indefinite in that the metes and bounds of "catheter-like" device are unclear. The term "like" is a relative one not defined by the claim, no single set of conditions is recognized by the art as being "catheter-like" and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claim 19 is vague and indefinite in that the metes and bounds of "distal end" are unclear. It is not clear to what the end is distal.

Claim 19 is vague and indefinite in that the metes and bounds of "to create a tissue space" are unclear. It is unclear what is intended by a "tissue space". Is this term used to designate a distinct structure, a space in the tissue, a space between tissues or something else?

Claim 31 is vague and indefinite in that the metes and bounds of "suitable" are unclear. The term "suitable" is a relative one not defined by the claim, no single set of conditions is recognized by the art as being "suitable" and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-7 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1) Nature of invention. The invention recites a method of treatment comprising locally penetrating and entering the body of an organ, organ component or tissue structure with minimal damage to obtain access to endomural zones of the organ. Furthermore, drugs are deposited in the midzone of the organ. The invention utilizes disciplines of pharmacology, cell biology, medical technology and clinical techniques.

2) **Scope of the invention**. While applicants recite a method of treatment, no specific disease targets or means of treatment are taught. The broad and unspecific nature of the target diseases and means of treatment exacerbates the invention.

3) **Number of working examples and guidance**. The instant method is primarily directed towards a method of treating conditions by placing therapeutics into the endomural zone. The method avoids invasive methods previously available. The endomural zone is described as the middle zone which comprises about 80% of the organ, organ component or tissue structure. By organ component or tissue structure applicant refers to vessels or ducts. In a

vessel for example, the endomural zone is also known as a lamina proper, submucosa, muscularis or media.

In the instant case, applicants propose methods and devices and kits directed toward delivery to the endomural zone with minimal collateral damage to healthy tissues or the target organ. Applicants provide three examples of devices that can be used to deliver agents to the endomural zone in figure 3, 4 and 5. These devices are comprised of hollow tubes such as catheters and delivery reservoirs filled with drugs, which are then expelled or dispersed into the endomural zone. The drugs are dispersed or expelled from the delivery means by an actuator, an activating or propelling agent or other means (see e.g. page 10, line 12-19). In addition the device can comprise sensors, guides, data storage etc (see e.g. page 10, line 20 through page 11, line 20). While the specification teaches multiple potential agents to deliver to "endomural zones", no specific targets or diseases to be treated are disclosed.

4) **State of Art**. The instant invention distinguishes itself from the prior art by specifically targeting the middle zone of an organ with drugs. In contrast the art is said to typically remove healthy or diseased tissue. Applicants propose use of devices, which are described as a hollow tube with a cutting or end penetrating means and a means of delivery to the endomural zone. Devices such as these appear to be well known in the art. Therefore, the instant invention advances the art by targeting specifically the endomural zone. However, it is not clear what step or part of the device delivers or targets the endomural zone specifically.

"Methods of treatment" are part of a high art. In order to treat a condition or disease, the disease must be known. This allows the target organ to be identified, the type and amount of drug to be applied, treatment intensity and accompanying drug schedules.

5) **Unpredictability of the art**. The lack of disclosure of the recited methods steps coupled with the unpredictable nature of the art render the invention unpredictable for use in treatment protocols. The lack of disclosure as to types of diseases, therapeutic endpoints, time schedules of delivery or immune suppression exacerbates the unpredictable nature of the invention.

Furthermore, endomural is not commonly used to distinguish the "middle zone" of the tissue. As guidance, applicants have described the endomural zone to correspond roughly to the central 80% of these structures. For example, the heart does not appear to have an "endomural zone" as evidenced in the accompanying drawings in Ross (Composition of the Heart, online article June 1999). By deduction, it can be concluded that the myocardium can be considered the endomural zone of the heart. It is unpredictable that applicants' definition of the endomural zone can be properly deduced for every organ, organ component and tissue structure.

6) **Summary**. The invention recites a method of treatment, which is performed with a device that allows delivery of drugs to the endomural zone. The device is used to minimally cause damage to collateral tissues while allowing drugs to be deposited directly in the endomural zone. The unpredictability of using the claimed invention is accentuated due to the lack of methods or processes disclosed in the instant specification that exacerbate a highly unpredictable art.

In view of predictability of the art to which the invention pertains and the lack of: undue experimentation would be required to practice the claimed methods with reasonable expectation of success, absent a specific and detailed description in the specification. Given the above analysis of the factors which the courts have determined are critical in determining whether a

claimed invention is enabled, it must be concluded that the skilled artisan would have had to have conducted undue unpredictable experimentation in order to practice the claimed invention.

Summary of endomural zone

The instant specification has described the endomural zone as the middle zone of an organ, organ component or tissue structure. As guidance, applicants have described the endomural zone to correspond roughly to the central 80% of these structures. In the heart, the myocardium fits this description as evidence in the accompanying drawings in Ross (Composition of the Heart, online article June 1999). Specifically, as evidenced in the drawings depicting the layers of the heart, the endocardium and epicardium surround the myocardium. The myocardium is roughly 80% of the heart layer. In the spinal cord, the lateral corticospinal tract appears to be in the area of the spinal cord that can be considered the endomural zone as evidenced by William et al (The Human Brain: Dissection of the Real Brain, January 1997, Chapter 1). Roughly 80% of the spinal cord is comprised of central cord, which encompasses the lateral corticospinal region (see figure).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6, 7, 15-18, 20-23, 25, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman (US 6,585,716 B2; see entire document).

Altman teaches a drug delivery device for methods of treating the heart for injecting therapeutic agents into the myocardium. The delivery device has a guidance system and a hollow penetrating element i.e. a needle attached to a catheter (see e.g. bridging paragraph col 3-4). Furthermore, sensors can be used with the device for electrical sensing (see e.g. col 5, line 65-67). Drugs are stored in a reservoir attached to the catheter and pumped automatically into the lumen of the drug delivery catheter through the penetrating element into the target (see e.g. col 5, line 15-39). Drugs used include growth factors and peptides and angiogenesis agents (see e.g. col 5, line 48-56 and col 4, line 1).

Claims 1-3, 6, 7, 15-18, 20-23, 25, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman (US 6,102,887; see entire document).

Altman teaches a catheter system for injecting therapeutic agents into the body through a distensible penetrating element with a chamber for holding the agent (se e.g. abstract). Specifically, the device is designed to penetrate the endocardium and inject drugs deep into the myocardium (see e.g. col 3, line 9-25). The penetrating end is a hollow tube such as a needle (see e.g. col 4, line 11-12). The drug delivery tube is comprised of polymers (see e.g. col 4, line 41-45) and drug delivery is driven by osmotic pumps or piston chambers (see e.g. col 6, line 40 through col 7, line 12) and is guided by a guiding catheter (see e.g. col 12, line 61-63). Furthermore, an expansile cutter is included with the device. This expansile cutter is comprised of an expanding prong fixation that is sharpened to penetrate and spread the tissue (see e.g. col 9,

line 22-440). Numerous agents are envisioned for delivery such as small molecules and macromolecules such as growth factors (see e.g. col 11 line 1 through 30).

Claims 1-3, 6, 14-16, 18, 20-25, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Haim et al, (US 6,309,370 B1; see entire document).

Haim et al teach an apparatus for intracardiac administration of growth factors into the myocardium (see e.g. abstract and col 3, line 24-42). The apparatus is minimally invasive and comprises a catheter with a distal end for insertion into the heart and a series of sensors for guidance, a position sensor and a optical sensor and one for identification of sites, a physiological sensor, a pressure sensor, an ultrasound sensor (see e.g. col 3, line through col 6, line 28). The drug delivery device comprises a hollow needle, which is inserted into the heart with a laser beam that conveys a wave-guide to create channels into which the drugs are deposited (see e.g. col 5, line 20-21 and col 6, line 41-44). Then the drugs are delivered by pump (see e.g. col 7, line 25-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (US 6,585,716 B2; see entire document) or Altman (US 6,102,887; see entire document) or Haim

et al, (US 6,309,370 B1; see entire document) in view of Benjamin and McMillan (Circ Res, 1998, Vol 83, pages 117-132; see entire document).

Applicants claim a method, devices and kits for treatment comprising locally penetrating and entering the body of an organ to gain access to an endomural zone. The device deposits drugs such as heat shock proteins into the endomural zone.

The teachings of Altman, Altman and Haim et al are described above and are applied as before except; neither Altman, Altman and Haim et al teach use of heat shock proteins.

Benjamin and McMillan teach that HSP enhances the speed of recovery of the Ischemic Heart (see e.g. page 119, col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drugs and growth factors taught by Altman, Altman and Haim et al with the HSPs taught by Benjamin and McMillan because Altman, Altman and Haim et al et al teach that it is within the ordinary skill of the art to deliver drugs to the myocardium to treat cardiac vascular disease and because Benjamin and McMillan teach that it is within the ordinary skill of the art to enhance recovery of an ischemic heart with administration of hsps. One would have been motivated to do so in order to receive the expected benefit of improved myocardial function, preserved metabolic functional recovery, reduction of infarct size (see e.g. page 119, col 2). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brosamle et al (The Journal of Neurosciences, 2000, Vol 20:21, pages 8061-8068; see entire document) in view

of Altman (US 6,585,716 B2; see entire document) or Altman (US 6,102,887; see entire document) or Haim et al, (US 6,309,370 B1; see entire document).

Applicants claim a method, devices and kits for treatment comprising locally penetrating and entering the body of an organ to gain access to an endomural zone. Applicants recite a use of kits comprising devices and a void filling material for nerve regeneration.

Brosamle et al teach the use of a device in which recombinant humanized IN-1 Fad antibody is delivered through by a pump through a catheter to the intrathecal space of the spinal cord. Specifically, a small hole in the dura matter was made and a catheter connected to a small osmotic pump was inserted into the subdural space close to the lesion (see e.g. figure 4). Following administration of rIN-1 Fab induced regeneration of transected spinal cord axons was induced (see e.g. page 8065, col 1, paragraph 3).

Brosamle et al do not teach that the device has an end penetrating or cutting means with which the device is inserted into the endomural zone.

The teachings of Altman, Altman and Haim et al are described above and are applied as before.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the device and methods of treatment for nerve regeneration of Brosamle et al with the device of Altman, Altman and Haim et al because Brosamle et al teach that it is within the ordinary skill of the art to administer drugs through a catheter into the subdural space for infusion into a lesion and because Altman, Altman and Haim et al et al teach that it is within the ordinary skill of the art to use a drug delivery device that delivers drugs into the depths of the tissue. One would have been motivated to do so in order to receive the expected benefit of

minimally invasive delivery of drugs in a local sustained manner for more effective drug effects (see e.g. US 6,309,370, col 2, line 50 through col 3, line 11). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GERRY LEFFERS
PRIMARY EXAMINER

Maria B Marvich, PhD
Examiner
Art Unit 1636

July 9, 2004